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DECLARATION FOR PATENT APPLICATION

As the below-named inventors, we hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled DIAGNOSIS AND THERAPY OF ANTIBODY-MEDIATED INFLAMMATORY AUTOIMMUNE DISORDERS, the specification of which

\_\_\_\_\_ is attached hereto as Attorney Docket No. \_\_\_\_\_).

XX was filed on January 3, 2002  
as Application Serial No. 10/038,509  
(Attorney Docket No. P-HR 5214)

and was amended on (or amended through) \_\_\_\_\_.  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

Under Sec. 1.56, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It

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Serial No.: 10/038,509  
Filed: January 3, 2002  
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establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (a) Opposing an argument of unpatentability relied on by the U.S. Patent and Trademark Office, or (b) Asserting an argument of patentability.

I hereby claim the benefit under Title 35, United States Code, § 120 of the prior United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 that became available between the filing date of the prior application(s) listed below and the filing date of this continuation-in-part application:

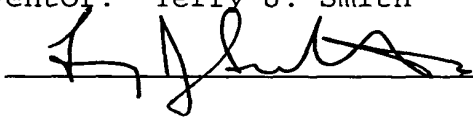
<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
10/046,651	October 19, 2001	Pending
09/684,601	October 6, 2000	Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Terry J. Smith

Inventor's signature: 

Date: 7/27/02

Residence: Manhattan Beach, California

Citizenship: USA

Mailing Address: 2415 Crest Drive  
Manhattan Beach, California 90266

20030509 0900



Inventor's signature: William W. Clark

Mailing Address: 13 Butternut Road  
Westford, Massachusetts 01886

103809



PATENT  
Our Docket: P-HR 5214

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Smith and Cruikshank )  
Serial No. 10/038,509 )  
Filed: January 3, 2002 )  
For: DIAGNOSIS AND THERAPY )  
OF ANTIBODY-MEDIATED )  
INFLAMMATORY AUTOIMMUNE )  
DISORDERS )

Commissioner for Patents  
Washington, D.C. 20231

Sir:

SMALL ENTITY STATEMENT

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association,

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Inventors: Smith and Cruikshank  
Serial No.: 10/038,509  
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trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months.

"Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

### (3) Nonprofit organization:

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C), (D).

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Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE ("Party").

Persons empowered to sign include an inventor him- or herself or an authorized officer of the assignee, where the assignee has at least an undivided part interest in the application or patent.

§ 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, each party having rights in the invention is listed below:

BOSTON UNIVERSITY SCHOOL OF MEDICINE  
HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE

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Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

June 12, 2002

Date

Kenneth P. Trevett

Name: Kenneth P. Trevett, J.D.

Title: President/CEO

HARBOR-UCLA RESEARCH  
AND EDUCATION INSTITUTE  
1124 West Carson Street  
Torrance, California 90502

20060505





PATENT

Our Docket: P-HR 5214

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Smith and Cruikshank )  
Serial No.10/038,509 )  
Filed: January 3, 2002 )  
For: DIAGNOSIS AND THERAPY )  
OF ANTIBODY-MEDIATED )  
INFLAMMATORY AUTOIMMUNE )  
DISORDERS )

Commissioner for Patents  
Washington, D.C. 20231

Sir:

**SMALL ENTITY STATEMENT**

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**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association,

Inventors: Smith and Cruikshank  
Serial No.: 10/038,509  
Filed: January 3, 2002  
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trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months.

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Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

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A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

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I hereby assert that I am empowered to sign on behalf of TRUSTEES OF BOSTON UNIVERSITY ("Party"). Persons empowered to sign include an inventor him- or herself or an authorized officer of the assignee, where the assignee has at least an undivided part interest in the application or patent. § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, each party having rights in the invention is listed below:

HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE  
TRUSTEES OF BOSTON UNIVERSITY

Inventors: Smith and Cruikshank  
Serial No.: 10/038,509  
Filed: January 3, 2002  
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Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

8/28/02

Date

MATTHEW J. BURNS  
ASSISTANT TREASURER  
BOSTON UNIVERSITY



Name: Matthew J. Burns

Title: Assistant Treasurer

TRUSTEES OF BOSTON UNIVERSITY  
108 Bay State Road  
Boston, Massachusetts 02215

COPY

SOLE

ASSIGNMENT

This Assignment is made by Terry J. Smith of Manhattan Beach, California, Assignor, to Harbor-UCLA Research and Education Institute, Assignee, having a place of business at 1124 West Carson Street, Torrance, California 90502.

WHEREAS, Assignor is a joint inventor of a new and useful DIAGNOSIS AND THERAPY OF ANTIBODY-MEDIATED INFLAMMATORY AUTOIMMUNE DISORDERS, for which an application for United States Letters Patent was filed on January 3, 2002, in the United States Patent and Trademark Office, bearing Serial No. 10/038,509 and identified as Attorney Docket No. P-HR 5214;

WHEREAS, Assignor believes that Assignor is one of the original joint inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entirety of assignor's right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor sells, assigns, and transfers to Assignee, the entirety of assignor's right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications and any Letters Patent that may be granted for said invention in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignor agrees that, upon request and without further compensation, but at no expense to Assignor, Assignor and Assignor's legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for

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Serial No.: 10/038,509  
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perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

Assignor represents and warrants that Assignor has not granted and will not grant to others any rights inconsistent with the rights granted herein.

Assignor authorizes and requests that any United States or foreign Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation or reissue application, be issued to Assignee, its successors and assigns, as the assignee of the entire interest in said invention.

IN WITNESS WHEREOF, Assignor has executed this Assignment on the date(s) provided below.

Assignor: Terry J. Smith

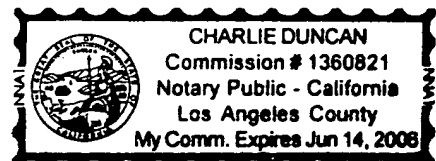
Terry J. Smith 7/27/02  
Signature Date

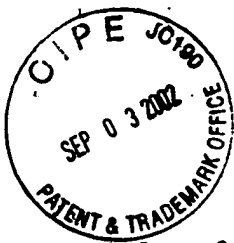
STATE OF California )  
COUNTY OF Los Angeles )

On July 27, 2002, before me, Charlie Duncan, Notary Public, personally appeared Terry J. Smith, personally known to me - OR - ✓ proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS by hand and official seal.

Charlie Duncan  
(Signature of Notary)



STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application: DIAGNOSIS AND THERAPY OF ANTIBODY-MEDIATED INFLAMMATORY AUTOIMMUNE DISORDERS

Application Ser. No.: 10/038,509

Filed: January 3, 2002

Inventor(s): Terry J. Smith and William W. Cruikshank

Attorney Docket No.: P-HR 5214

HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE, a non-profit organization, states that it is a joint assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventors of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

Date: July 19, 2002

Signature: 

Name: Kenneth P. Trevett, J.D.

Title: President/CEO



STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application: DIAGNOSIS AND THERAPY OF ANTIBODY-MEDIATED INFLAMMATORY AUTOIMMUNE DISORDERS

Application Ser. No.: 10/038,509

Filed: January 3, 2002

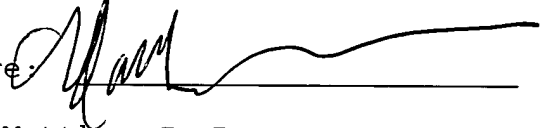
Inventor(s): Terry J. Smith and William W. Cruikshank

Attorney Docket No.: P-HR 5214

TRUSTEES OF BOSTON UNIVERSITY, a University, states that it is a joint assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventors of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

Date: 8/28/02

Signature: 

Name: Matthew J. Burns

Title: Assistant Treasurer

MATTHEW J. BURNS  
ASSISTANT TREASURER  
BOSTON UNIVERSITY

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